SEPA

Note to Correspondents

FRIDAY, MARCH 1, 1991

EPA sent letters to 262 pesticide companies yesterday informing them that the Agency has received information alleging that Craven Laboratories of Austin, Texas may have falsified residue and environmental fate studies which were conducted for pesticide companies in support of their pesticide tolerances and registrations.

EPA is currently taking steps to conduct a comprehensive, chemical-by-chemical, internal review of all use of data from Craven Laboratories. In the letter to the pesticide companies, EPA requested the companies to identify every study submitted to the Agency which reflects any work done by Craven Laboratories; to identify any other information or data on hand or which can be gathered which might assist the Agency to validate a regulatory decision based on Craven data; and also to identify what steps can be taken to provide new data to the Agency if necessary.

"We consider the allegations to be very serious and will determine as quickly as possible whether certain studies, or all studies, conducted by Craven Laboratories in support of pesticide tolerances or registrations will need to be replaced," said Linda Fisher, EPA Assistant Administrator for Pesticides and Toxic Substances. "Of paramount importance," Fisher continued, "is the analysis of specific chemicals to resolve questions about the safety of the food supply raised by these allegations; however, based on the information now available to EPA, we do not believe there is a risk to public health or the environment."

Craven Laboratories conducts primarily residue chemistry studies designed to determine the amounts of pesticide residues which remain on food. To EPA's knowledge the laboratory did not conduct toxicology studies. The residue studies conducted by Craven Laboratories are performed under contract for pesticide

R-34

(more)

companies and are used by EPA in deciding whether to set tolerances (allowable residue levels) on food and whether to register (approve the sale of) pesticide products.

Last summer EPA received a report of alleged data manipulation from a pesticide industry task force whose members hired Craven to perform a market-basket survey which EPA had requested. At approximately the same time, information about falsification of data by Craven Laboratories was reported to EPA by The task force survey measured the amount of another source. pesticide residues in various food products obtained from grocery stores. During the course of performing a quality assurance audit of the laboratory, a task force representative received allegations that data performed for the task force had been manipulated. subsequent task force inspection and data audit of the laboratory revealed allegations concerning the validity of other studies.

EPA conducts periodic inspections of laboratories that submit data supporting pesticide registrations to ensure compliance with its Good Laboratory Practices (GLP) regulations. Residue chemistry data submitted to the Agency such as that performed by Craven became subject to EPA's GLP regulations in 1989. In June, 1990, Craven Laboratories was scheduled for an inspection to occur in September due to the chemicals it was testing. Based on the early September inspection, the GLP inspection team turned over the matter to EPA's criminal enforcement personnel in Dallas for further investigation. This event, coupled with previous reports, resulted in EPA obtaining a search warrant so that Craven records could be inspected and copied to determine compliance with GLP and other provisions of the Federal Insecticide, Fungicide and Rodenticide Act. A criminal investigation has ensued which precludes EPA from revealing details of some of the information on the Craven Laboratories issue that has been obtained.

For further information, call Al Heier at (202) 382-4374.

John Kasper, Director Press Services Division (202) 382-4355

R-34

END : of Note to Comes pardents